Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

13 August 2018

English only

2018 Meeting
Geneva, 4-7 December 2018

Meeting of Experts on Assistance, Response and Preparedness
Geneva, 14-15 August 2018
Item 4 of the provisional agenda
Practical challenges facing the implementation of Article VII, and possible solutions

Strengthening Article VII: International Cooperation and Assistance in Preparing for and Responding to Biological Incidents

Submitted by the United States of America

Summary

While progress has been made in addressing impediments to the provision or receipt of international assistance in response to an attack or unusual disease outbreak, we can still do more to address barriers to sharing and receiving public health and medical assistance. For example, States Parties could continue to strengthen national and international Emergency Operations Center capacities, reinforce policies and frameworks for sharing medical countermeasures, and address national barriers to sending or receiving public health and medical personnel in response to public health emergencies.

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I. Background: the importance to Article VII of Preparedness

1. In 2013, the United States submitted a working paper to the Meeting of Experts outlining a number of the challenges to providing international assistance in responding to infectious disease outbreaks regardless of their source, noting that these challenges will affect States Parties' ability to respond to a violation of the BWC under Article VII. A range of logistical, informational, and legal/regulatory issues can impede a State Party's ability to identify the need for assistance, to provide assistance, or to receive and use offered assistance. Preparedness is not a prerequisite for a country to request assistance under Article VII, but it may well be a prerequisite for being able accept and make use of such assistance.

2. Many States Parties have made progress since 2013 in identifying and addressing specific impediments to international preparedness and response; however, much work remains to overcome the legal, regulatory and logistical barriers that impede the ability of governments to both provide and receive international assistance during biological emergencies. Challenges to implementation of Article VII remain, and collectively we must continue to identify ways to address them.

3. The United States has sought to contribute to Parties' consideration of preparedness and response efforts since the 2016 Review Conference, as well as in the previous intersessional process. We have focused our efforts on identifying impediments and opportunities for the provision and acceptance of international assistance during public health emergencies. For example, we completed a multi-year research project on the response to the 2014 Ebola outbreak and how that response might have been altered if there had been a deliberate component, or if the outbreak had reached into non-permissive environments, and submitted a working paper to the 2016 BWC Review Conference on that project's findings. We also submitted a paper in collaboration with Canada and the United Kingdom at the 2017 Meeting of States Parties that sought to identify how governments and non-governmental entities can prepare for collaborative action in the event of the use of biological weapons.

4. The 2018-2020 intersessional process provides us with an opportunity to continue our focused discussions on international preparedness and response. But these discussions are not taking place in a vacuum. The United States' efforts to find solutions to the challenges of providing and receiving public health assistance are one component of a broader global approach to strengthening global health security, aligned with the priorities of the Biological Sub-Working Group of the Global Partnership Against the Spread of Weapons of Mass Destruction and obligations under the International Health Regulations (2005) (IHR) for States Parties to collaborate and develop capacity to respond to public health emergencies of international concern. Through our commitments under the Global Health Security Agenda (GHSA) to accelerate IHR implementation efforts, we are assisting 31 countries and a regional partner to improve their ability to prevent, detect, and respond to infectious disease threats, in an effort to improve capacities around the world. Other international stakeholders have taken a similar approach to identifying and addressing challenges to the deployment of international assistance in ways that are integrated with efforts to strengthening global health security. During our discussions of these challenges in this and other BWC-related meetings, it is important to remember that parallel conversations are taking place in other fora, and we should seek to link these efforts where we can.

II. Strengthening Coordination in Emergencies

5. A key element in the development of rapid, effective response capacities for assessing, containing, mitigating, and recovering from biological threats is the development of an interconnected global multi-sectoral network of Emergency Operations Centers (EOCs). EOCs play a critical role in coordinating the response to biological threats and in requesting, receiving, and coordinating support from domestic and international partners. To fulfill this role, EOCs need both fully trained staff that can meet core competencies for emergency management and systems in place that can be fully activated within two hours of an alert. The United States continues to strengthen its own national and sub-national EOC capacities, leveraging insights and recommendations from global tools and models like the WHO Public Health Emergency Operations Centre (PHEOC) framework, the IHR and the IHR Joint External Evaluation tool, and national EOC improvement processes, like the Emergency Management Accreditation Program (EMAP). BWC States Parties should be encouraged to establish EOCs, and should seek to share information, best practices, and operational models for EOCs, in order to strengthen national and international EOC capacities to coordinate responses to biological threats.

III. Barriers to Sharing Countermeasures and Personnel

6. Effective response to a biological incident also requires the international community to improve global access to medical and non-medical countermeasures, as well as medical and public health personnel that can be rapidly deployed during an emergency. This requires States Parties to strengthen their capacity to produce or procure equipment, medication, vaccines and technical expertise, and to strengthen policies, regulations and operational frameworks for sharing medical countermeasures (MCMs), products, and personnel across borders during biological emergencies. The *Operational framework for deployment of the World Health Organization smallpox vaccine emergency stockpile in response to a smallpox event*, developed by WHO in collaboration with the Global Health Security Initiative, was released in 2017 and serves as a model for identifying and addressing the legal, regulatory, and logistical barriers to deploying MCMs internationally. Building on this effort, WHO is developing an operational framework for deploying and receiving other medical countermeasures, which will further advance global progress on this issue. Additionally, the WHO Emergency Use Assessment and Listing (EUAL) process was established and used during the Ebola outbreak in West Africa and Zika epidemic in the Americas. In these cases, the EUAL provided national regulatory authorities and other global stakeholders with advice on use of certain MCMs during a public health emergency, based on available quality, safety, and performance data. These efforts illustrate the progress by states, international organizations, and others in establishing global frameworks and processes to address the challenges to the international deployment of MCMs. However, states must still consider how to effectively implement their own national policies, processes, and regulations to ensure that they can deploy and/or receive and use MCMs during public health emergencies.

7. The launch of the WHO Emergency Medical Teams (EMT) Initiative under the WHO Health Emergencies Programme has been an important step forward in increasing global capacities to rapidly deploy medical personnel in response to public health emergencies. The Global Outbreak Alert and Response Network (GOARN) is another key global tool for requesting and identifying personnel to support investigation of and rapid response to disease outbreaks. However, states should continue to identify and address their national barriers to sending or receiving public health and medical personnel in response to public health emergencies, such as national funding to support the deployment of or receipt of foreign public health and medical personnel, liability protection, recognition of licensure

and medical credentials, and logistics to include lodging, food, and other needed services for responding health professionals.

IV. Conclusion

8. Our interconnected world makes it easier for serious illnesses to spread faster than ever before. States Parties will, unfortunately, continue to experience catastrophic public health disasters, and the international community will need to have the will and capacity to work together to rapidly respond in order to save as many lives as possible. It is imperative that States have the necessary internal capabilities to respond efficiently and effectively to future disease outbreaks, whether they are deliberate, accidental, or natural in origin. The BWC intersessional process provides an important forum for States Parties to share experiences and build stronger partnerships to improve response efforts. We hope that States Parties will take advantage of the Meeting of Experts to engage in a frank, open discussion about the challenges they face in providing and receiving assistance during public health emergencies so that we can identify and work toward solutions in subsequent meetings of the intersessional process. We also hope that States will take action to address the issues that we have already identified by implementing legal and regulatory frameworks and enhancing logistical capabilities.

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Procedures, including the establishment and use of the assistance database to improve the prompt and efficient response without preconditions to a request of assistance by a State Party under Article VII, and coordination and cooperation among States Parties and with relevant international and regional organizations such as World Health Organization (WHO), World Organisation for Animal Health (OIE), Food and Agriculture Organization (FAO), as appropriate

Investigations of Alleged Biological Weapons Use: Overlap with Public Health Assistance under Article VII of the Biological and Toxin Weapons Convention

Submitted by the United States of America

Summary

Allegations of biological weapons use should be investigated by an organization that can maintain its independence and objectivity in order to determine whether an outbreak is deliberate or natural and, if necessary, to attribute responsibility. There are several mechanisms by which such an investigation could be initiated. It is likely that such an investigation would occur concurrently with an international public health effort to provide assistance under Article VII. There might well be areas of overlap between these parallel efforts, and entities seeking to carry out their missions might encounter challenges in areas such as preservation of evidence. MOUs could play an important role in mitigating tensions between different organizations. To the extent possible, it would be useful to identify and define in advance the procedures, guidelines, and standards of evidence that would be necessary for both an investigation of alleged use and a public health assistance mission.

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I. Introduction: Investigations of Alleged Use

1. In cases of alleged biological weapons use, it may prove difficult to determine whether an outbreak of disease is a naturally occurring biological event or the result of an intentional attack, let alone to determine who was responsible for the attack. The political context could become heated, with charges and counter-charges, and the security situation unstable or dangerous. There is clear value, therefore, in having allegations of biological weapons use investigated by an organization that can maintain its independence and objectivity, and in having the procedures, guidelines, and standards of evidence identified in advance to the extent possible while maintaining flexibility to suit the circumstances of the case. Such an investigation of alleged use can help to confirm whether an outbreak is deliberate or natural and, in the event of an intentional attack, can help to attribute responsibility.

2. Any investigation into allegations of biological weapons use, however it is initiated, would occur concurrently with public health efforts to identify and mitigate the disease outbreak. Guidance is needed to ensure that an investigation of alleged use and a public health assistance mission, which may be running in parallel, do not hamper each other's work. This is particularly true if the State Party that is the victim of the biological attack initiates a criminal investigation at the domestic level, in addition to requesting an international investigation of alleged use. Those conducting such investigations might well need to collaborate where possible in order to ensure efficiency and avoid duplication of effort, but would also need to retain their independence in order to maintain credibility. This paper identifies some of the possible areas of overlap and potential challenges for multiple entities carrying out their missions in the aftermath of an alleged use of a biological agent, and offers some suggestions for how they might work together more effectively.

II. Processes for Investigating Allegations of Biological Weapons Use

3. An international investigation might be conducted through several different processes. For example, the so-called "United Nations Secretary-General's Mechanism" (UNSGM) was recognized by the 2006 BWC Review Conference as an existing international apparatus for conducting impartial investigations into cases of alleged use. As we noted in our 2016 working paper, "Possibilities for strengthening the international community's ability to investigate alleged use" (BWC/Conf.VIII/PC/WP.10), this mechanism itself could be initiated in several ways, all of which are fully consistent with the provisions of the BWC.

4. Other mechanisms also exist by which an investigation into alleged use of biological weapons could be initiated. Article VI of the BWC provides that:

> "Any State Party to this Convention which finds that any other State Party is acting in breach of obligations deriving from the provisions of the Convention may lodge a complaint with the Security Council of the United Nations. Such a complaint should include all possible evidence confirming its validity, as well as a request for its consideration by the Security Council."

Article VI also requires States Parties to cooperate in carrying out a Security Council-initiated investigation. It is also possible that an investigation conducted by the UN Secretary-General could inform an Article VI complaint to the Security Council; these procedures are not mutually exclusive. And, of course, neither of these mechanisms would limit the ability of a victim state to launch its own investigation through domestic law

enforcement, which could play a role in determining attribution and/or holding the perpetrators accountable in a domestic court.

III. Training

5. The timely and efficient international investigation of alleged use of biological weapons will rely on the technical knowledge and skills of experts who would be called upon to carry out fact-finding missions. Since 2009, several BWC Member States, including Australia, Canada, Sweden, Switzerland, Germany, Denmark, France, the United States and the United Kingdom, have sponsored specialized training courses, exercises, and workshops for experts on the Secretary-General's roster. Many other countries have contributed to the ability of the Secretary-General to conduct an investigation by nominating experts and consultants to the roster.

6. In 2011, the World Health Organization (WHO) and the United Nations signed a Memorandum of Understanding (MOU) on the support that the WHO could provide to the Secretary-General's Mechanism. Among other activities, WHO agreed to provide support in training the experts on the Secretary-General's Mechanism roster by providing presentations and materials on the procedures and logistics of outbreak investigation for public health emergencies and associated training modules for experts. In addition, WHO and the United Nations agreed to "extend to each other invitations for participation in relevant training and educational activities." MOUs have also been reached with the Organisation for the Prohibition of Chemical Weapons (OPCW), Interpol, and the International Organisation for Animal Health (OIE). It can be expected that similar measures of cooperation would be extended to an investigation under the aegis of the Security Council.

7. In the event of an alleged biological weapons attack, cooperation at both the domestic and international levels between public health and security authorities in the early stages of a response is critical both to containing the outbreak and identifying those responsible. However, many countries may not have the necessary capacity or infrastructure to promote collaboration between these different sectors. Moreover, joint training between public health authorities and local or national law enforcement is particularly lacking. This could lead to friction and gaps in information-sharing if these entities are simultaneously responding to the outbreak. These problems could in turn jeopardize the effectiveness and credibility of international investigations of alleged use. Joint training opportunities can enable public health and law enforcement officials to better understand each discipline's roles and responsibilities, enabling them to build working relationships, which is crucial for the identification and investigation of a biological weapons attack.

IV. Interviews

8. Both public health and law enforcement investigations into the alleged use of biological weapons require interviews with cases/victims and other witnesses. Such interviews can be an important element of a fact-finding mission; they can be crucial for the collection, assessment, or corroboration of information. From an epidemiologic perspective, interviews are key for determining the source of infections and mitigating the spread of disease.

9. Joint interviews involving public health, security authorities, and/or international investigators may allow representatives from each discipline the opportunity to collect and assess information according to their needs. When joint interviews are not possible, human,

animal, plant, or food health, law enforcement, and international investigation personnel could collaborate in advance to synchronize their interview questions, or share data from their interviews to support their investigations.

10. In some cases, international or national investigators might find medical, epidemiological, or other patient data helpful or even critical in seeking to attribute responsibility. Yet public health authorities may be concerned about legal liabilities for releasing patient information without the patient's consent, or about potentially jeopardizing trust in their organizations' neutrality. It would be beneficial for actors involved in both missions to discuss possible challenges to sharing information, such as protecting patient privacy, before beginning the interview process, or, ideally, before the initiation of the investigations. States Parties may wish to consider whether there are national-level mechanisms they could implement to facilitate such discussions.

V. Preservation of evidence

11. In the event of a deliberate attack, it is important to preserve evidence that could help in the investigation. The provenance of samples may be a key element of attributing an attack to a particular actor. It is critical that all involved in a response to a potential biological attack, including field teams and laboratories, are aware of the procedures to preserve forensic evidence, which may differ from traditional public health sampling and analytical methodologies.

12. Conflicts might arise between public health authorities and criminal or international biological weapons investigators regarding the collection, analysis, and preservation of samples or materials for evidence. For example, public health providers might be concerned that their ability to collect and analyze samples would be compromised by investigators' efforts to preserve evidence and maintain strict chain of custody requirements in order to ensure that future accountability measures can withstand scrutiny. Similarly, investigators might be reluctant to share forensic data if sharing that information could compromise their investigation, even though such data may be useful or even essential to public health authorities in mitigating the effects of a disease outbreak.

13. While priority must be given to the protection of public health and safety, it is important for experts, investigators, and public health officials to discuss these competing objectives ahead of time and identify mitigation strategies.

VI. Role of Formal Agreements

14. The MOUs between the UN and other international organizations such as WHO and OIE certainly go a long way in alleviating some of the potential areas of friction between an investigation under the Secretary-General's Mechanism or under the aegis of the Security Council and a public health mission. Possible cooperative activities include the secondment of public health experts to the UN Office of Disarmament Affairs; the provision of information on health and disease control methodologies; and the making available of equipment for outbreak investigation.

15. At the domestic level, the Global Health Security Agenda (GHSA) Action Package Respond-2 calls for GHSA member countries to link public health and security authorities to conduct a multi-sectoral response to a biological event of suspected or confirmed deliberate origin. GHSA members are encouraged to develop and implement MOUs or other similar frameworks to conduct and support joint criminal and epidemiologic investigations in the event of biological incidents suspected to be of deliberate origin. Such frameworks can be tremendously beneficial in facilitating effective information sharing and

ensuring that investigations and public health assistance missions reinforce and complement, rather than compromise, each other.

VII. Conclusions

16. We acknowledge the efforts of a number of countries in strengthening the Secretary-General's Mechanism and identifying possible challenges that an investigation might face. We support taking reasonable steps to strengthen the UN Secretary-General's Mechanism's operational capacity to investigate allegations of BW use. We are also pleased that the Secretary-General's May 2018 disarmament agenda includes efforts to strengthen the standing capacity to conduct independent investigations of alleged use of biological weapons.

17. As noted above, there are several mechanisms by which an alleged attack might be investigated, and several organizations that might be involved in the response, at both the international and domestic level. In summary, it is essential that public health organizations with the responsibility to respond to a disease outbreak and entities with a law enforcement- or internationally-initiated investigation mandate have good working relationships, opportunities to develop contacts with each other, and fora in which to discuss protocols and procedures in a hypothetical biological attack scenario.

18. Many BWC States Parties have expressed interest in establishing guidelines or procedures for a State Party to request assistance under Article VII, and we welcome this effort. Should the Meeting of Experts seek to develop such guidelines, we urge States Parties to keep in mind the potential sources of tension that an Article VII assistance mission might encounter with an investigation into alleged use, and consider whether any of the guidelines we put in place might help to mitigate these tensions.

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Practical challenges facing the implementation of Article VII, and possible solutions

A set of guidelines and formats to assist a State Party, if required, when submitting an application for assistance in the framework of Article VII

Procedures, including the establishment and use of the assistance database, to improve the prompt and efficient response without preconditions to a request of assistance by a State Party under Article VII, and coordination and cooperation among States Parties and with relevant international and regional organizations such as World Health Organization (WHO), World Organisation for Animal Health (OIE), Food and Agriculture Organization (FAO), as appropriate

Exploration of approaches by which States Parties, individually or collectively, might contribute to the strengthening of international response capabilities for infectious disease outbreaks, whether natural or deliberate in origin

Assistance, response and preparedness

Submitted by the Bolivarian Republic of Venezuela on behalf of the Non-Aligned Movement and other States Parties to the Biological and Toxin Weapons Convention

I. Introduction

1. NAM and other States Parties to the BWC welcome that during the 2017 Meeting of States Parties to the Biological Weapons Convention (BWC) reached consensus on an intersessional programme from 2018 to 2020.

2. The purpose of the ISP is to discuss, and promote common understanding and effective action on those issues identified for inclusion in the intersessional programme. The work in the intersessional period will be guided by the aim of strengthening the implementation of all articles of the Convention in order to better respond to current challenges.

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3. The Group of NAM and other States Parties to the BWC highlights that the Inter-sessional Period (ISP) is important in the absence of detailed treaty provisions for implementation. We believe that the ISP should aim at achieving progress in the implementation of all articles of the Convention in a balance, comprehensive and consensus based approach.

II. Agenda item 4: Practical challenges facing the implementation of Article VII, and possible solutions

4. NAM and Other States Parties welcome the discussions on strengthening Article VII, as part of the current inter-sessional program.

5. According to Article VII of the Convention, if a State Party is exposed to danger as a result of the violation of the Convention, and requests assistance, all States Parties undertake to provide or support assistance.

6. NAM strongly reaffirms that national preparedness of States Parties and their prompt access to new methods and novel diagnostic technologies and equipment for detection and quick response to any possible biological attack or diseases outbreaks play an important role in providing assistance to States Parties. The rapid pace of novel bio-threats against humans, animals and plants requires rapid responses and enhanced national capacity prior to any biological attacks against the States Parties.

III. Agenda Item 5: A set of guidelines and formats to assist a State Party, if required, when submitting an application for assistance in the framework of Article VII

7. The Group notes the working paper (BWC/MSP/2018/MX.4/WP.3) submitted by South Africa to the MX4 outlining that assistance in accordance with Article VII would be additional to and following the assistance provided by international organisations and should be humanitarian in nature.

IV. Agenda Item 6: Procedures, including the establishment and use of the assistance database, to improve the prompt and efficient response without preconditions to a request of assistance by a State Party under Article VII, and coordination and cooperation among States Parties and with relevant international and regional organizations such as World Health Organization (WHO), World Organization for Animal Health (OIE), Food and Agriculture Organization (FAO), as appropriate

8. Although this Article has not been yet invoked, the international community should be prepared to face such situation well in advance and to dispatch emergency assistance in case of use of bacteriological (biological) or toxin weapons, and also to provide humanitarian assistance in case of the threat of use of such weapons, to the requesting State Party. Assistance undertakings and support should be commensurate with effective actions that ensure timely coordination and delivery of assistance to the victim State Party in conformity with the request for assistance.

9. To this end, a detailed procedure and mechanism for a timely, effective and adequate response needs to be developed. In this context, the following elements may, amongst others, be considered in the development of such a mechanism:

- Assistance means coordination and delivery of assistance to the requesting State Party,
- The request or appeal for assistance should be immediately transmitted to all States Parties and relevant international organizations for coordination and delivery of emergency and humanitarian assistance and support,
- Preparing an inventory of the types of assistance that the States Parties could provide including, inter alia, expertise, information, protection, detection, decontamination, prophylactic and medical and other equipment,
- Establishing a data bank containing freely available information concerning various means of protection against bacteriological (biological) and toxin weapons as well as such other relevant information as may be provided by States Parties,
- Information on the kind of assistance that States Parties could provide in response to a request for assistance; the States Parties make take necessary measures the fullest possible efforts to provide prompt assistance,
- Providing the equipment related to the means of protection against the use of biological weapons to the requesting State Party without undue restrictions,
- Establishing a fund for assistance to concerned States Parties in particular to developing countries,
- Promoting capacity building through more active cooperation with relevant regional and sub-regional organizations that have mandates relevant to assistance and protection against biological weapons. Such cooperation could include joint exercises and training, including by the use of e-learning modules.

10. The Group underlines that all mechanisms and measures adopted for full, effective and non-discriminatory implementation of Article X of the Convention, shall facilitate assistance and support to States Parties for rapid and timely surveillance, detection, contaminant, diagnosis, treatment and mitigation of diseases, in particular infectious diseases in accordance with the provisions of the Convention.

11. The Group notes the working paper (BWC/MSP/2018/MX.4/WP.4) submitted by South Africa that an application for assistance in terms of Article VII, independent of United Nations Security Council approval, raises some practical questions and also lists information that should be provided in a request for assistance. The Group notes some of the issues raised in the South African working paper may require further discussion and decision by the States Parties to help in the strengthening of the implementation of Article VII of the Convention.

V. Agenda Item 8: Exploration of approaches by which States Parties, individually or collectively, might contribute to the strengthening of international response capabilities for infectious disease outbreaks, whether natural or deliberate in origin

12. The UN and other international organizations could also play an important role in coordinating, and mobilizing, and delivering the required support and assistance. In this

respect, upon the request of the concerned State Party, the capacities and experiences of UN and relevant international organizations should be identified and used, within their mandates.

13. To mitigate the consequences of the use of biological and toxin weapons, the national capacity of States Parties in particular developing countries, should also be developed and strengthened. In this regard, the NAM group emphasizes that one of the most effective approaches to support Article VII implementation is that each State Party should facilitate, and shall have the right to participate in the fullest possible exchange of equipment, materials and scientific and technological information and know-how concerning means of protection against bacteriological (biological) and toxin weapons. The States Parties should also have the right to conduct research into, develop, produce, acquire, transfer or use means of protection against bacteriological (biological) and toxin weapons, for purposes not prohibited under the Convention. Towards this end, developed countries should assist developing States Parties through providing required technology and resources, as well as sharing experiences, expertise and laboratory cooperation.

14. NAM reiterates its support for the recommendation of the 8th Review Conference on Article VII. In this regard, it reaffirms that timely assistance under Article VII is a legal obligation of States Parties. While noting that States Parties' national preparedness contributes to international capabilities for response, investigation and mitigation of outbreaks of disease, NAM reaffirms that this should not be a imposed as precondition for either provision or receipt of assistance.

15. NAM believes that the lack of a comprehensive Protocol to strengthen implementation of all aspects of the Convention has created a gap in the provision of prompt and effective assistance under Article VII to States Parties to the BWC.

16. In conclusion, let me highlight that the main objective of this Article is to provide assistance to the affected people and to minimize and contain the risks to the health, safety and security of others, in close collaboration with the exposed State Party. However, the best way to prevent such incidents is to ensure full compliance with the prohibition on the development, stockpiling and use of such weapons, including through the establishment of a compliance and verification mechanism under the Convention.